DEPARTMENT OF VETERANS AFFAIRS **Research Service Policy Memorandum 23-43**
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404 **January 09, 2023**

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Procedures for Submission, Review and Approval of Research Projects

1. PURPOSE: The purpose of this SOP is to describe the procedures for submitting research projects to the Research and Development (R&D) Office, administrative processing by the R&D Office, and reviewing and approving of research projects by the R&D Committee and its subcommittees.

2. POLICY: The R&D Committee is responsible, through the Chief of Staff, to the Medical Center Director for oversight of and for maintaining high standards for the research program. The R&D Committee, as described in VHA Directive 1200.01 and South Texas Veterans Health Care System (STVHCS) Research and Development Committee Charter, is responsible for reviewing all research projects submitted to STVHCS. Research that meets the following criteria is defined as VA Research, and may not be conducted without R&D Committee approval:

a. The research is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property in space leased to or used by the STVHCS facilities.

b. The research enrolls subjects at STVHCS or uses STVHCS's nonpublic information to identify or contact human research subjects for research purposes.

c. The funds for the research activities are managed by STVHCS or its affiliated non-profit corporation, the

System (VAIRRS) instance of IRBNet (gov.irbnet

(f) Administrative staff will: 1) ensure that required FCOIs have been received from all study personnel serving in an investigator role (i.e., PI, Co-Investigators, or Sub-investigators) and contact PIs/study coordinators as needed if any are missing; 2) prepare the "FCOI Acknowledgement" form and bundle with the FCOIs for each study for the FCOI Administrator's reviews; and c)

(b) The final approval of the R&D Committee will only occur after all conditions have been met and applicable subcommittees have granted final approval. Once approved by the R&D Committee, the research becomes VA-approved research.

(c) Final approval will be granted for up to one year, not to exceed the IRB or IACUC expiration date (if applicable). Next "report due" and/or expiration dates will be recorded in IRBNet to generate the automated reminder notices the following year

(d) R&D administrators will document "Board" actions in IRBNet, prepare approval letters for signature by the ACOS for R&D, and upload these as Board documents in the R&D Committee workspace in IRBNet.

(e) The R&D Committee will communicate its decision in writing to the Principal Investigator and all decision letters will be posted as "board" documents in IRBNet. The Principal Investigator may initiate research activities only after receipt of a signed approval letter from the ACOS for R&D. The approval letter will include any conditions on which the approval is based, such as specific requirements for management of a FCOI.

b. **Continuing Review** Each research project under the sole oversight of the R&D Committee (no SRS or IRB) must be reviewed and approved by the R&D Committee annually. All other research projects will be administratively reviewed in the STVHCS R&D Administration "workspace" annually. Refer to the Research Service SOP for Protocol Management for VA Approved Human Subject Research Projects for additional information on the continuing review process for projects involving human subjects.

4. REFERENCES: VHA Directive 1200.01, VHA Directive 1200.05

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RESCISSION: Research Service Policy Memorandum 17-43, dated January 14, 2022

7. RECERTIFICATION: January 09, 2027

[Signature on File]

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ACOS for Research and Development